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APPLICATION

of

XIUGAO LIAO

for

UNITED STATES LETTERS PATENT

on

HIGH REFRACTIVE INDEX AND OPTICALLY CLEAR  
COPOLY(CARBOSILANE AND SILOXANE) ELASTOMERS

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HIGH REFRACTIVE INDEX AND OPTICALLY CLEAR  
COPOLY(CARBOSILANE AND SILOXANE) ELASTOMERS

Field of the Invention

The present invention is directed to high refractive index and optically clear elastomers, and ophthalmic lenses formed therefrom. More particularly, the invention relates to copoly(carbosilane and siloxane) elastomers.

Background of the Invention

The physiology of the human eye includes an anterior chamber located between the cornea, or outer surface of the clear part of the eye, and the iris, the pigmented portion of the eye that is responsive to light, and a posterior chamber, filled with vitreous humor. A crystalline lens, which includes a lens matrix contained within a capsular bag, is located behind the iris and separates the iris from the posterior chamber. The crystalline lens is attached to the ciliary muscle by cord-like structures called zonules. Lining the rear of the posterior chamber is the retina, the light sensing organ of the eye, that is an extension of the optic nerve. In young, healthy eyes, contraction and relaxation of the ciliary muscle shapes the natural crystalline lens to the appropriate optical configuration for focusing light rays entering the eye on the retina.

As the natural crystalline lens ages, however, the structure of the lens matrix of the crystalline lens changes, becoming hazy and relatively inflexible. Eventually, the hazing of the lens matrix may progress to the point where the lens is considered cataractous, which may seriously occlude the amount of light passing through the crystalline lens and ultimately onto the retina. Fortunately, modern surgical techniques have been developed which allow removal of the cataractous lens matrix so that light may once again pass unimpeded onto the retina.

Presently, a cataractous crystalline lens matrix is removed from an eye using a procedure whereby the cataractous natural lens matrix is extracted from the capsular bag of the lens through an anterior capsulotomy. Typically, the cataractous lens matrix is removed from the capsular bag through the anterior capsulotomy using phaco-emulsification and aspiration. Alternatively, the cataractous lens matrix may be removed using several other well known techniques whereby the cataractous material is broken up and aspirated from the

capsular bag. After extraction of the cataractous lens matrix, an intraocular lens may be implanted within the remaining capsular bag. However, while the procedure to remove the emulsified natural lens can be accomplished with about a three millimeter incision in the cornea, about at least a six millimeter incision is required to accommodate the full diameter of the intraocular lens to be implanted.

In order to reduce the size of the incision required for implantation of an intraocular lens, and thus limit the trauma to the eye, intraocular lenses made of relatively soft material that can be rolled, folded or otherwise deformed for insertion into the eye were developed, replacing conventional intraocular lenses made of relatively hard material, such as polymethylmethacrylate (PMMA). Soft intraocular lens must exhibit a number of important mechanical and physical properties to be suitable as an implant. For instance, soft intraocular lenses should have low glass transition temperatures so that they can be readily folded for implantation at room temperature. In addition, the thickness of the intraocular lens should be minimized in order to reduce the overall size of the folded or rolled lens. Thus, soft intraocular lenses should have a high refractive index so that the lenses will have the requisite refractory power at a minimal thickness. The lenses should also exhibit a high degree of softness to improve the foldability of the lenses, thereby reducing the size of the folded lens, while still retaining other mechanical properties, such as tensile strength and folding recoverability. Further, the lenses must be optically clear.

Prior art soft intraocular lenses made of silicone materials typically have very low glass transition temperatures (lower than  $-100^{\circ}\text{C}$ ), permitting them to be readily folded or rolled at room temperature. However, other properties of silicone lenses could be improved in order to minimize the size of the folded lens. It would be desirable to provide a silicone material for use as an intraocular lens that has a high refractive index and softness to reduce the size of the folded lens. It would also be desirable to provide a silicone material that has other properties suitable for use as an intraocular lens such as high folding recoverability and optical clarity.

What has been needed and heretofore unavailable, is a silicone material having improved properties, including a high refractive index, softness, optical clarity and excellent folding recoverability, for use in intraocular lenses. The present invention satisfies these needs and others.

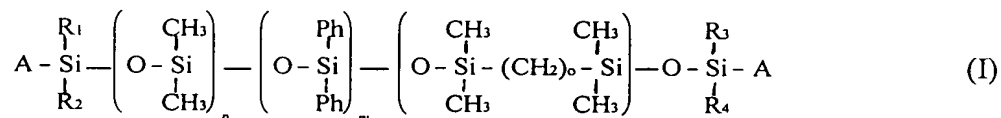
# SUMMARY OF THE INVENTION

The present invention provides copoly(carbosilane and siloxane) elastomers useful in the fabrication of ophthalmic lenses, including intraocular lenses and other implantable ocular devices, such as intraocular contact lenses.

In one embodiment, the copoly(carbosilane and siloxane) elastomer comprises a copolymer having carbosilane repeat units and siloxane repeat units. Each carbosilane repeat unit has a carbon chain with 2 to 12 carbon atoms. Each siloxane repeat unit may be individually selected from the group comprising dimethylsiloxane and diphenylsiloxane.

The copolymers of the present invention also have terminal alkynyl groups in one embodiment. More particularly, each terminal alkynyl group may be selected from the group consisting of vinyl, allyl, vinylphenyl, allylphenyl, vinylbenzyl and allylbenzyl.

In another embodiment, the copolymer has the structure (I):



wherein A is an alkynyl; R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, and R<sub>4</sub> are each a hydrocarbon group; Ph is a phenyl; n is an integer from 10 to 500; m is an integer from 5 to 100; o is an integer from 2 to 12; and p is an integer from 2 to 50.

In other embodiments, additional materials are also included in the elastomer to achieve desired properties. In one embodiment, the elastomer includes a platinum catalyst. In another embodiment, the elastomer includes a crosslinking agent, such as an organohydrosilane having multiple hydride groups or containing multiple hydride group polymers. More particularly, the crosslinking agent is a hydrodimethyl-terminated silazane in one embodiment. In yet another embodiment, a filler that is hexamethyldisilazane-treated silica and silicone resin material is added to the elastomer. Further, an ultraviolet (UV) light absorbing compound, such as allyl or methallyl functionalized benzotriazoles and benzophenones, may also be included in the elastomer.

The elastomers of the present invention have a high refractive index, at least about 1.43 in one embodiment. The elastomers also have excellent folding recoverability.

In one embodiment, an ophthalmic lens is formed from the copoly(carbosilane and siloxane) elastomers. In particular, the ophthalmic lens may be an intraocular lens. The ophthalmic lens may also be an intraocular contact lens or other implantable ocular device.

The elastomers of the present invention are particularly suited for use in ophthalmic lenses due to their high refractive index and optical clarity. The elastomers are also soft materials with excellent folding recoverability, permitting lenses formed therefrom to be folded or rolled to a minimal size for insertion. The elastomers also have high strength and flexibility and are photostable.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the drawings, which illustrate, by way of example, various embodiments, principles and features of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1A is a top view of an embodiment of an intraocular lens of the present invention, having an optic and a pair of haptics;

FIG. 1B is a side view of the embodiment of FIG. 1A;

FIG. 2A is a top view of an embodiment of an intraocular lens of the present invention having an optic and a pair of plate-type haptics; and

FIG. 2B is a side view of the embodiment of FIG. 2A.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to elastomers having a high refractive index and optical clarity, and ophthalmic lenses made therefrom. Specifically, the invention relates to copoly(carbosilane and siloxane) elastomers having a high refractive index and optical clarity that are suitable for implantation within an eye of a patient.

The elastomers of the present invention include a copolymer having carbosilane repeat units and siloxane repeat units. In one embodiment, each carbosilane repeat unit has a carbon chain with 2 to 12 carbon atoms. Generally, about 2 to 50 carbosilane repeat units are present in a chain of the copolymer, although more carbosilane repeat units, such as 50 or more, may